

FORMULATION OF AN ERODIBLE, GASTRIC RETENTIVE
ORAL DOSAGE FORM USING IN VITRO DISINTEGRATION TEST DATA

Erodible, gastric-retentive dosage forms are provided that are formulated using the *in vitro* drug release profile obtained with USP Disintegration test equipment rather than the USP Dissolution Apparatus. The invention is premised on the discovery that the USP Disintegration Test and modified versions thereof are far more predictive of the *in vivo* release profile for a controlled release dosage form than is the standard USP Dissolution Test, particularly controlled release dosage forms of the swellable, erodible type. The dosage forms generally comprise particles of a biocompatible, hydrophilic polymer having the active agent incorporated therein, wherein the particles are optionally but preferably compacted into a tablet or loaded into a capsule. The dosage forms can be used to deliver water-insoluble or sparingly soluble drugs as well as water-soluble drugs, providing that the latter are coated with a protective coating or contained in a protective vesicle.